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10/039,471	10/19/2001	Mark T. Martin	100391-02030	1031

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EXAMINER	
MEAH, MOHAMMAD Y	
ART UNIT	**PAPER NUMBER**
1652	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

klpatent@kramerlevin.com

Office Action Summary	Application No.	Applicant(s)	
	10/039,471	MARTIN, MARK T.	
	Examiner	Art Unit	
	MD. YOUNUS MEAH	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-20,23,26-29 and 32-45* is/are pending in the application.

4a) Of the above claim(s) *7-9 and 33-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 6, 10-20, 23, 26-29 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3, 6-20, 23, 26-29, 32-45 are pending. Claims 7-9, 33-45 remain withdrawn. Claims 1-3, 6, 10-20, 23, 26-29 and 32 were examined in the prior action. With supplemental amendment of this application, the applicant, on dates 3/04/08 amended claims 26.

Specification Objection

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code at paragraph 0250. See MPEP § 608.01.

Claim Rejections

35 U.S.C 112 second paragraph

Claims 17-20, 23, 26-29, 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is indefinite in the recitation of “non-naturally occurring enzyme” as all enzymes which occurred in nature are not known, some are known and some are not. Furthermore, the scope of what occurs in nature is constantly changing as enzymes that occur in nature overtime can be mutated and change its form.“ . For the sake of examining purpose examiner define the term as any enzyme or its mutated form.

Rejection of claim 26 is withdrawn after amendment of the claim by the applicant.

35 U.S.C 112 1st paragraph Written Description requirement.

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-20, 23 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
Claims 17-20, 23 and 26 are directed to any non-naturally occurring enzyme molecule that modify any biological target molecule or TNF-alpha, IL-4, IL-6 or VEGFR2 type target molecule by attaching any label or any beta-lactam antibiotic type target molecule via formation of any bond between said target molecule and label
A search of the original specification and abstract did not find the words "non-naturally occurring enzyme" and only one occurrence of the word "naturally", on page 7, line 8. It is maintained that not only does the specification not teach methods of modifying enzymes to non-naturally occurring ones; it does not provide even the mention of the words. Therefore it is maintained that one of ordinary skill in the art reading the instant specification would not conclude that applicant had possession of the claimed invention.

Claims 1-3, 6, 10-20, 23, 26-29 and 32 are rejected under 35 U.S.C. 112, first paragraph for lack of Written Description for the reasons set forth in the previous office action mailed 09/07/2007.

Claims 1-3, 6, 10-20, 23, 26-29 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-3, , 11-12 are directed to methods of modifying any biological molecule by attaching any label using any catalytic antibody via formation of any bond between said target molecule and label. Claim 10 is directed to methods of modifying any TNFalpha, IL-4, IL-6 or VEGFR2 molecule by attaching any label using any catalytic antibody via formation of any bond between said target molecule and label. Claims 6, 8-9,13-16, are directed to methods of modifying any biological target molecule by attaching beta-lactam antibiotic type label molecule catalyze via formation of any bond between said target molecule and label by any catalytic antibody. Claims 17-20, 23, 26-29, 32 are directed to any enzyme or catalytic antibody molecule that modify any biological target molecule or TNFalpha, IL-4, IL-6 or VEGFR2 type target molecule by attaching any label or any beta-lactam antibiotic type target molecule via formation of any bond between said target molecule and label.

These claims comprise three constituents: target molecule, label and a catalytic

antibody or enzyme that attach said label to the target molecule by forming covalent bond between target moiety to the label molecule. Though specification describes target molecule and label molecule, the specification does not describe how a particular bond can be formed between the target molecule and the label molecule. A biomolecule comprises any antibody, protein, enzyme, hormone, DNA, RNA, lectin, glycoprotein, etc, each class of these compounds having variety of bond forming functional groups. Same is true for the label molecule. Production of specific catalytic antibody depends on the structure of the specific transition state analog (Tewfik et al. from IDS). In most cases, even a single hapten molecule of a transition state analog (for forming or cleaving a bond) elicits multiple catalytic antibodies (Jana et al. from IDS). Since most target bimolecule (antibody, protein, enzyme, hormone, DNA, RNA, lection, glycoprotein, etc) contain multiple functional groups capable of forming a bond with a functional group on the label (amino, hydroxyl, phosphonate group (and moreover formation a bond of this group with a functional group of the label also depend on the overall structure of the biomolecule and the label as a whole), determining suitable transition state analog is unpredictable for these groups and hence the production of a suitable catalytic antibody is unpredictable also (Janda et al.). Claims 17-20, 23, 26-29, 32 are directed to any enzyme having no structural limitation modifies any biological target molecule or TNFalpha, IL-4, IL-6 or VEGFR2 type target molecule by attaching any label or any beta-lactam antibiotic type molecule via formation of any bond between said target molecule and label. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large

number of enzymes with variable structures broadly encompassed by the claim. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of enzyme. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species (in this case, a genus of biomolecule having a genus of functional group capable of forming a bond with a functional group on the label), requires a precise definition, such as by structure, formula or chemical name of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species, which are adequately described, are representative of the entire

genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

There is no structure-function correlation with regard to the members of the genus of target molecules and their functional groups capable of forming a bond with a functional group on the label (as most biomolecules comprise multiple of this groups and formation of bonds via these groups is dependent on overall structure of the target). The specification discloses the structure of a few antigens and suggestion of eliciting catalytic antibodies against them. However neither the applicants nor prior art ever teach forming any bond between a functional group of target biomolecule with a functional group on the label introducing into a host a target and label and then eliciting catalytic antibody. The specification lacks description of identifying characteristics or properties or structure of the target molecule and the any functional group(s) (as most target comprise multiple of this groups and formation of bonds via these groups with functional group of label molecules a CMAB. Therefore, one of skill in the art would not recognize that applicants' were in possession of the claimed invention. In the case of enzyme that recited in claims 17-20, 23, 26-29, 32, there is no structure-function correlation with regard to the members of the genus of enzyme molecule claimed. The specification discloses mutated beta-lactamase without defined structure. Therefore one of skill in the art would not recognize from the disclosure that applicants' were in possession of the claimed invention.

Applicants' are referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Applicants' arguments, on pages 8-14 of their amendment, against rejection of claims 1-3, 6, 10-20, 23, 26-29 and 32 under 35 U.S.C 112, first paragraph written description requirement are acknowledged. Applicants argue that specification gives ample example of biological target molecules and also gives examples of labels. Specification teaches an example wherein an antibody attaches a label to target molecule. The instant claims recite methods of modifying any biological molecule by attaching any label using any catalytic antibody via formation of any bond between said target molecule and label. One example is not a representative of the entire genus that the instant claims recite. Generation of catalytic antibody or artificial enzyme molecule is not routine in the art. Most target biomolecules ("protein, peptide, nucleic acid, carbohydrate, cell, subcellular particle, virus, steroid, [and] lipid") and label molecules comprise multiple functional groups. Bond formation between different functional group of biological target molecule and functional group of label molecule is dependent on the nature of functional groups as well as overall structure and nature of the biomolecule, (Murray et al.). Therefore an antibody catalyzes formation of one type of bond between one specific functional group of a target molecule and functional group of a label molecule will not catalyze the bond formation between other type functional group of a target molecule and functional group of a label molecule. As previously stated and as stated in the specification, catalytic antibodies are generally

made using transition state analogs to the reaction to be catalyzed. Some transition state analogs or other hapten will produce catalytic antibodies and some will not, as discussed in earlier action. The instant claims are drawn to attaching any label to a target molecule consisting of any "protein, peptide, nucleic acid, carbohydrate, cell, subcellular particle, virus, steroid, [and] lipid". While a particular target molecule might be known and a particular label might be known, the claims are not limited to any particular ones. The specification certainly does not teach any hapten that will produce a catalytic antibody, so that even if the particular target molecule and label were known, the particular hapten that would produce a catalytic antibody that would attach a label to the target molecule is not taught in the specification. Therefore it is maintained that one of ordinary skill in the art reading the instant specification would not conclude that applicant had possession of the claimed invention. Similarly, it is maintained that one of ordinary skill in the art would conclude that applicant did not have possession of the "non-naturally occurring enzyme" of claims 17-20, 23 and 26. It is pointed out that "non-naturally occurring enzyme[s]" do not fall within the scope of enzymes of biological origin. Therefore it is maintained that one of ordinary skill in the art reading the instant specification would not conclude that applicant had possession of the claimed invention.

35 U.S.C 112 1st paragraph Enablement requirement

Claims 1-3, 6, 10-20, 23, 26-29 and 32 are rejected under 35 U.S.C. 112, first paragraph for lack of Written Description for the reasons set forth in the previous office action mailed 09/07/2007.

Claims 1-3, 6, 10-20, 23, 26-29 and 32 are rejected under 35 U.S.C. 112, first paragraph are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for any enzyme or catalytic antibody molecule capable of catalyzing formation of any bond between any functional group of any biological target molecule or any TNFalpha, IL-4, IL-6 or VEGFr2 type target molecule and any functional group of any label or any beta-lactam antibiotic type label molecule and methods of modifying any biological molecule by attaching said label using said catalytic antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention.

Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breath of the claim(s).

These claims are so broad to encompass any enzyme or catalytic antibody

molecule capable of catalyzing formation of any bond between any functional group of any biological target molecule or any TNFalpha, IL-4, IL-6 or VEGFr2 type target molecule and any functional group of any label or any beta-lactam antibiotic type label molecule and methods of modifying any biological molecule by attaching said label using said catalytic antibody. Most target biomolecules and label molecules comprise multiple functional groups. Bond formation between different functional group of biological target molecule and functional group of label molecule is dependent on the nature of functional groups as well as overall structure and nature of the biomolecule, (Murray et al.). Therefore an antibody catalyzes formation of one type of bond between one specific functional group of a target molecule and functional group of a label molecule will not catalyze the bond formation between other type functional group of a target molecule and functional group of a label molecule.

The specification discloses the structure of a few label molecules and few target molecule and suggestion of eliciting catalytic antibodies against them. Even each of these target biomolecules comprise multiple of various functional groups (various amino, hydroxyl groups). However the applicants have not isolated a single catalytic antibody. As explained above the structure of the hapten is very crucial in antibody catalysis and production of specific catalytic antibody depends on the structure of the specific transition state analog. Production of CMAB for specific bond formation between functional group of biological target molecule and functional group of label molecule is dependent on the nature of functional groups as well as overall structure of the biomolecule. Specific bond formation between two functional groups of two

organic compounds and catalyzing it by a CMAB elicited by known hapten molecule ***in-vitro*** is well known to the skilled artisan; However, finding a suitable transition state analog for the formation of bond between one of the enormous number of functional groups of target biomolecule and functional group of label and producing CMAB for said reaction, and finding which among enormous variants of said CMAB and said groups as claimed by applicants has desired properties (producing desired CMAB, effecting desired biological function) requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the enormous numbers of functional groups of target biomolecule and functional group of label are suitable for production of CMABs, knowledge of a suitable transition state analog of said bond, and knowledge of which CMABs are suitable to elicit said function (said bond formation). Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute **undue** experimentation.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any enzyme or catalytic antibody molecule capable of catalyzing formation of any bond between any functional group of any biological target molecule or any TNFalpha, IL-4, IL-6 or VEGFr2 type target molecule and any functional group of any label or any beta-lactam antibiotic type label molecule and methods of modifying any biological molecule by attaching said label using said catalytic antibody. The scope of the claims must bear a reasonable

correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of substances having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

As discussed in the prior office action in detail and above again, these claims are so broad to encompass any non-natural enzyme or catalytic antibody molecule having any structural limitations, catalyzing formation of any bond between any functional group of any biological target molecule or any TNF-alpha, IL-4, IL-6 or VEGFr2 type target molecule and any functional group of any label or any beta-lactam antibiotic type label molecule and methods of modifying any biological molecule by attaching said label using said catalytic antibody the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention.

Applicants' arguments, on pages 14-17 of their amendment, against rejection of claims 1-3, 6, 10-20, 23, 26-29 and 32 under 35 U.S.C 112, first paragraph enablement are acknowledged. Applicants argue that generation of antibody based on skill in the art, detailed description in the specification is not undue. It is true that generation of antibody by immunization with a specific desired antigen is not undue but as discussed in prior action and below again, generation of catalytic antibody or artificial enzyme molecule is not routine in the art and as these claims are so broad to encompass any artificial enzyme or catalytic antibody molecule catalyzing formation of any bond

between any functional group of any biological target molecule or any TNF-alpha, IL-4, IL-6 or VEGFr2 type target molecule and any functional group of any label or any beta-lactam antibiotic type label molecule and methods of modifying any biological molecule by attaching said label using said catalytic antibody, there require undue experimentation to find out which of any antibody or artificial enzyme will catalyze bond formation among these diverse group of functional groups of target molecules.

Most target biomolecules and label molecules comprise multiple functional groups. Bond formation between different functional group of biological target molecule and functional group of label molecule is dependent on the nature of functional groups as well as overall structure and nature of the biomolecule, (Murray et al.). Therefore an antibody catalyzes formation of one type of bond between one specific functional group of a target molecule and functional group of a label molecule will not catalyze the bond formation between other type functional group of a target molecule and functional group of a label molecule.

The specification discloses the structure of a few label molecules and few target molecule and suggestion of eliciting catalytic antibodies against them. Even each of these target biomolecules comprise multiple of various functional groups (various amino, hydroxyl groups). However the applicants have not isolated a single catalytic antibody. As explained in the prior action in detail, the structure of the hapten is very crucial in antibody catalysis and production of specific catalytic monoclonal antibody (CMAB) depends on the structure of the specific transition state analog. Production of CMAB for specific bond formation between functional group of biological target

molecule and functional group of label molecule is dependent on the nature of functional groups as well as overall structure of the biomolecule. Specific bond formation between two functional groups of two organic compounds and catalyzing it by a CMAB elicited by known hapten molecule ***in-vitro*** is well known to the skilled artisan; However, finding a suitable transition state analog for the formation of bond between one of the enormous number of functional groups of target biomolecule and functional group of label and producing CMAB for said reaction, and finding which among enormous variants of said CMAB and said groups as claimed by applicants has desired properties (producing desired CMAB, effecting desired biological function) requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the enormous numbers of functional groups of target biomolecule and functional group of label are suitable for production of CMABs, knowledge of a suitable transition state analog of said bond, and knowledge of which CMABs are suitable to elicit said function (said bond formation). Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute **undue** experimentation.

Thus, applicants have <u>not</u> provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any enzyme or catalytic antibody molecule capable of catalyzing formation of any bond between any functional group of any biological target molecule or any TNF-alpha, IL-4, IL-6 or VEGFr2 type target molecule and any functional group of any label or any beta-lactam antibiotic type

label molecule and methods of modifying any biological molecule by attaching said label using said catalytic antibody. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of substances having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

CLAIM Rejection - 35 U.S.C 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Rejection of claims 17-20, 23, 26-29, 32 under 35 U.S.C. 102(b) as being anticipated by Tanaka et al. (Tet lett 1999, pp 8063-8066 from IDS) remain. Tanaka et al. teach catalytic antibody which catalyzes formation of acyl-enzyme bond between beta-lactamase (target) and beta-lactam type compound (label) in doing so modulate the activity of the beta-lactamase.

Applicant's argument, that Tanaka et al. does not anticipate each and every element of the claim is not found to be true because like applicant (figure 1 and paragraph 0055-0056 of the specification) Tanaka et al. teach a catalytic antibody (an enzyme) catalyzes the formation of acyl-enzyme bond between beta-lactamase and

beta-lactam type compound. When a substrate (beta-lactam type compound) covalently attach to the enzyme (in this case, beta-lactamase) it inactivates the enzyme.

Claims 17-20, 23, 26-29, 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Nardone et al. (JBC 1986, vol. 261, pp 12128-12133). Nardone et al. teach BaMHi endonuclease and methylase wherein the methylase methylates cytosine of a DNA molecule in doing so modulates the DNA molecule so that it is resistant to cleavage by endonuclease.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat. T. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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